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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,969	07/21/2005	Tomoharu Suga	44342.024000	2010
<div>7590 GERARD F DIEBNER DREIER LLP 499 PARK AVENUE NEW YORK, NY 10022</div>			<div>EXAMINER AHMED, HASAN SYED</div>	
			<div>ART UNIT 1615</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 09/07/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/542,969

Applicant(s)

SUGA ET AL.

Examiner

Hasan S. Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.<sup>9</sup>

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/28/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of applicants': (a) remarks, which were filed on 13 March 2007; (b) declaration, which was filed on 14 June 2007; and (c) request for continued examination, which was filed on 14 June 2007.

\* \* \* \* \*

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 March 2007 has been entered.

\* \* \* \* \*

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto, et. al. (U.S. Patent No. 5,576,014).

Mizumoto, et. al. disclose an intraorally rapidly disintegrating tablet (see col. 1, lines 9-28).

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The disclosed tablet is the instant tablet as claimed:

- the core granule (comprising a medicament and a sugar) coated with a pharmaceutical disintegrating agent of instant claim 1 (see col. 7, lines 19-46; col. 13, lines 39-43);
- the disintegrating agent of instant claim 2 (see col. 13, line 40);
- the sugar of instant claim 3 (see col. 7, lines 19 and 20);
- the average particle diameter of instant claim 4 (see col. 7, lines 50 and 51); and
- the tablet thickness of instant claim 5 (see col. 5, line 37).

\* \* \* \* \*

#### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed on 14 June 2007, which, *inter alia*, restates the remarks filed on 13 March 2007, is insufficient to overcome the rejection of claims 1-5 based upon Mizumoto as set forth in the last Office action for the reasons stated in the "response to arguments" section, below.

\* \* \* \* \*

#### ***Response to Arguments***

Applicant's arguments filed 13 March 2007 have been fully considered and are not persuasive.

1. Applicants argue that the Mizumoto reference does not disclose a tablet where the core itself is coated with a pharmaceutical disintegrating agent. See remarks (filed on 13 March 2007) page 2, and declaration (filed on 14 June 2007) page 2.

Examiner respectfully disagrees. Mizumoto explains that an active agent may be mixed with a saccharide and other additive agents (making up the core); this mixture may then be coated using an aqueous solution of high moldability saccharide (see col. 13, lines 3-7). Mizumoto goes on to state that the solution of high moldability saccharide used to coat the core may also contain disintegrant (see col. 13, lines 62-65). Thus, Mizumoto's core granule will be coated with a disintegrating agent.

2. Applicants argue that the instant application and prior art attain hardness and quick disintegration by different means. See declaration (filed on 14 June 2007) page 3.

Examiner respectfully submits that hardness is not claimed by the instant application.

As to attainment of quick disintegration, the recitation "rapidly disintegrating tablet" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

3. Applicants argue that hydroxypropylcellulose is not recited in instant claim 2. See declaration (filed on 14 June 2007) page 3.

Examiner respectfully submit the Office action dated 14 December 2006 cites the disintegrating agent at col. 13, line 40 of Mizumoto (see Office action, page 2), which recites carboxymethylcellulose calcium as a disintegrating agent, which is one of the disintegrating agents recited in instant claim 2.

4. Applicants argue that the disclosure of Mizumoto at col. 13, lines 58-65 does not make clear that a disintegrant may be added to the core granule in a coating process and that the cited recitation "does not make sense." See remarks (filed on 13 March 2007) page 2, and declaration (filed on 14 June 2007) page 4.

Examiner respectfully submits that when the recitation of Mizumoto at col. 13, lines 58-65 is read in conjunction with the recitation at col. 13, lines 3-7, it is clear that Mizumoto discloses a disintegrant added to a core granule in a coating process.

5. Applicants argue that the "fifth process" and "sixth process" do not disclose or suggest a core granule coated with a disintegrant. See remarks (filed on 13 March 2007) pages 2-3, and declaration (filed on 14 June 2007) pages 4-5.

The "fifth process" recites coating with a high moldability saccharide. The "sixth process" recites coating with an active ingredient followed by granulation with a high moldability saccharide. Mizumoto explains at col. 13, lines 58-65 that these coating processes may include a disintegrant.

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***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N. SHEIKH  
PRIMARY EXAMINER